REMARKS

I. Claim Changes

Claims 29 to 45 have been canceled and new claims 46 to 59 have been added. These claims include independent composition claim 46 and independent method claim 57. New independent composition claim 46 more particularly points out and more distinctly claims the inventive composition than canceled claim 29.

New claim 46 claims an injectable oligomer-polymer composition, which is a liquid. Claim 46 defines the composition with "closed-ended" or "consisting of" wording that excludes other ingredients than those recited. Claim 46 claims a liquid composition *consisting of* at least one bioactive substance, at least one solid polymeric hydrxycarboxylic acid ester and at least one liquid oligomeric hydroxycarboxylic acid ester.

The claimed injectable liquid oligomer-polymer composition advantageously does not include prior art organic solvents, such as ethanol, or even water, but instead includes a liquid oligomeric hydroxycarboxylic acid ester. There are thus no biocompatibility problems in the case of the claimed invention.

New dependent claims 47 to 55 are injectable composition claims based on canceled dependent composition claims 33 to 43. Dependent claim 56 is a claim for the implant made from the injectable compositions. New independent method claim 57 is based on canceled method claim 45. Claim 58 is a dependent method claim depending on claim 57 and dependent claim 59 is a claim for the coagulum made by the method claimed in claim 57.

A patent was granted on the corresponding European Patent Application EP 1 152 776 B1 on May 22, 2002. A copy of this granted European Patent has been filed.

II. Indefiniteness Rejection

Claims 33 and 34 were rejected under 35 U.S.C. 112, second paragraph, for indefiniteness.

Claims 33 and 34 have been canceled, obviating their rejection under 35 U.S.C. 112. However new claims 47 and 48 contain the same subject matter as canceled claims 33 and 34. It appears that this rejection was primarily due to the use of different printer fonts for the letters designating the formulae in the text and in the formulae itself. This deficiency has been corrected in the above new claims 47 and 48. Also the wording of the new claims has been checked to make certain that antecedent basis for claim terms has been maintained.

In addition, it is noted that the wording "R for variables m, n, o, p, q and r is identical or different and represents" means that the R groups within the radicals that are bounded by the brackets with the subscripts m, n, o, p, q and r may be different from each other and are one of the listed carbon- and hydrogen-containing groups. In other words, the R groups are treated as if they are subscripted by m, n, o, p, q or r when within the brackets so subscripted. This reduces the amount of subscripting and has basis in the specification and would be understood by one skilled in the chemical arts.

For the foregoing reasons and because of the change in the wording of new claims 46 to 59, it is respectfully submitted that none of the new claims 46 to 59 should be rejected under 35 U.S.C. 112, second paragraph, for indefiniteness.

III. Rejection of Claims as Obvious over Dunn, et al, RE 37,950

Claims 29 to 45 were rejected as anticipated under 35 U.S.C. 102 (b) by Dunn, et al, or under 35 U.S.C. 103 (a) as obvious from Dunn, et al.

Dunn, et al, disclose a method of making an implant for delivery of a bioactive substance, such as a drug (claims 1 to 5); an injectable liquid composition for making the implant (claims 6 to 13) and a solid composition including a bioactive substance, such as a drug (claims 16 and following). Also see summary starting in column 4. The injectable liquid composition for making the implant includes a solid water-insoluble biodegradable polymer dissolved in a water-soluble organic solvent. The water-soluble organic solvent can be N-methyl-2-pyrrolidone (NMP), acetone, methyl acetate, etc, as claimed in claim 9. NMP is particularly preferred as solvent. The solid water-insoluble polymer can include polylactides, polygycolides, etc. as claimed in claims 2 and 3.

Implants of the type produced by the methods of Dunn, et al, are similar to those of U.S. Patent 4,938,763, which are described in the background section of the specification on pages 1 and 2.The implants of the foregoing reference and Dunn, et al, are produced by injecting a liquid composition that includes a water-soluble organic solvent, as described above, especially NMP (N-methyl-2-pyrrolidone – see examples of Dunn, et al, in columns 9 and following and

column 5, line 46 to 58; claim 6). The particular water-soluble organic solvents used by Dunn, et al, however are physiologically active. Their physiological effects are not well known or completely established. Thus it is desirable to make the implants by other methods that do not include injecting one of these water-soluble solvents, especially NMP, whose chemical structure differs significantly the solid polymer included in the solvent.

New injectable polymer-oligomer composition claim 46 claims an injectable composition, which is a liquid, as is convenient for injection. Claim 46 excludes the particular water-soluble organic solvents of claim 9 of Dunn, et al, such as NMP and in fact also water, from the claimed injectable composition because it is drafted with "consisting of" wording. The same is true of step a) of the method claim 57 – the liquid composition injected in the claimed method is the composition of claim 46.

The composition of claim 46 is a *liquid* because it includes a *liquid* oligomeric polyhydroxy acid ester that is used effectively as solvent or dispersant for the solid polymeric ester ingredient. For example, see example 10 on pages 15 and 16 of applicants' specification.

It is well established that each and every limitation of a claimed invention must be disclosed in a single prior art reference in order to be able to reject the claimed invention under 35 U.S.C. 102 (b) based on the disclosures in the single prior art reference. See M.P.E.P. 2131 and also the opinion in ***In re Bond***, 15 U.S.P.Q. 2nd 1566 (Fed. Cir. 1990).

Thus new claims 46 to 59 avoid anticipation by Dunn, et al, because

Dunn, et al, **do not teach or suggest** that the injectable liquid composition comprises a *liquid* oligomeric polyhydroxy acid ester that is used effectively as solvent or dispersant. Thus Dunn, et al, do not teach or suggest the critical limitations in claims 46 and 57 and do not anticipate the subject matter of these claims.

Use of the *liquid* oligomeric polyhydroxy acid ester, which is made by chemical reactions in non-aqueous solvents according to examples 1 to 9 in applicants' specification, as solvent or dispersant provides special advantages as explained in applicants' specification on e.g. pages 7 and 10. The oligomeric and polymeric esters of hydroxycarboxylic acids are biodegradable and can be used to make a sterile liquid injectable composition without use of low molecular weight solvents and/or plasticizers, which may produce side effects.

It is well established by many U. S. Court decisions that to reject a claimed invention under 35 U.S.C. 103 there must be some hint or suggestion in the prior art of the modifications of the disclosure in a prior art reference or references used to reject the claimed invention, which are necessary to arrive at the claimed invention. For example, the Court of Appeals for the Federal Circuit has said:

> "Rather, to establish obviousness based on a combination of elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant...Even when obviousness is based on as single reference there must be a showing of a suggestion of motivation to modify the teachings of that reference.." ***In re Kotzab***, 55 U.S.P.Q. 2nd 1313 (Fed. Cir. 2000). See also M.P.E.P. 2141.

In the case of the instant application the Dunn reference does *not suggest* a liquid injectable composition for making an implant including a *liquid* oligomeric polyhydroxy acid ester used as solvent or dispersant.

Thus it is respectfully submitted that **none** of the new claims 46 to 59 should be rejected as anticipated under 35 U.S.C. 102 (b) by Dunn, et al, or under 35 U.S.C. 103 (a) as obvious from Dunn, et al.

IV. Specification Changes

Some minor errors, including an error in the numbering of the structural formulae and a punctuation error, have been corrected in the paragraph running from pages 3 to 5 of the applicants' specification.

V. Information Disclosure Statements

An information disclosure statement citing two U.S. Patent references and two EP references was filed with the original U.S. National Stage application papers. However the initialed form PTO-1449 or PTO-A820 indicating that the cited references had been considered did not accompany either of the two Office Actions issued in the above-identified U.S. Patent Application. Return of the initialed form PTO-1449 or PTO-A820 with the next response from the Patent Office is respectfully requested.

Also consideration of all prior art references including those in a foreign language to the extent possible is requested.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

Michael J. Striker,
Attorney for the Applicants
Reg. No. 27,233